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Trial Registration: Understanding and Preventing Reporting Bias in Social Work Research

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Abstract

Randomized controlled trials are considered the gold standard for evaluating social work interventions. However, published reports can systematically overestimate intervention effects when researchers selectively report large and significant findings. Publication bias and other types of reporting biases can be minimized through prospective trial registration that is now an accepted part of medical research. In this article, we explain how trial registration can promote ethical and valid trials in social work, and we explain how social work researchers can register trials. We conclude that journal editors should ask authors to report trial registration numbers in all reports of randomized trials in social work.

Keywords

randomized experiment, outcome study, evidence-based practice, literature review, systematic review, meta-analysis, methodology, methodological article, RCT

Introduction

Randomized controlled trials in social work are increasingly common (Montgomery & Mayo-Wilson, 2009). They allow researchers to estimate what would have happened if participants had not received an intervention, thus providing evidence of the intervention's effects. Because trial results can vary for many reasons, including chance, comprehensive syntheses of many trials (i.e., systematic reviews) provide the best overall evidence of true effectiveness.

Well-conducted trials and reviews are considered the gold standards in primary and secondary research (Schulz, 1996), but both can be vulnerable to bias. For example, trials may account for missing data in their analyses because participants who do not return outcome measures differ from participants who complete trials, that is, *attrition bias*. For systematic reviews, missing trial data have the same effect as missing participant data, and recent studies show that *reporting bias* may be the most important source of bias in intervention science today. Fortunately, reporting bias can be minimized through a simple process, that is, *trial registration*.

Reporting Bias

Systematic reviews minimize bias by including all eligible trials, including unpublished literature. This reduces the impact of *publication bias*, which occurs when studies with large, positive results are more likely to be published than studies with small, nonsignificant results (Dickersin, 1997). Contacting authors further reduces *selective outcome reporting*, which occurs when trials are partially published; that is, certain outcomes are chosen for publication based on their results (Hutton & Williamson, 2000).

Publication bias and selective outcome reporting can occur when researchers do not intend to mislead. For example, researchers may believe that negative results are uninteresting, and they may believe that positive outcomes are more important than null results. For social work as a whole, however, the effects of these reporting biases are analogous to conducting trials in which outcomes are reported only for people who improve.

Overestimating the effects of health and social interventions can have serious consequences. For example, a review comparing published and unpublished studies of antidepressants for children demonstrated that published trials favor medication, but unpublished data suggest that risks outweigh benefits (Whittington et al., 2004). Consequently, the United States now warns that children taking antidepressants might experience

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increased suicidal ideation (U.S. Food and Drug Administration [FDA], 2004), and the United Kingdom now recommends that antidepressants not be used routinely for children (National Institute for Health and Clinical Excellence, 2005).

Failing to publish entire trials is the most obvious type of publication bias, but research also demonstrates subtle biases contribute to inaccurate beliefs about intervention effects. Positive trials are more likely to be published quickly (Ioannidis, 1998), repeatedly (Tramer, Reynolds, Moore, & McQuay, 1997), in English (Egger et al., 1997), and in high-impact journals (Easterbrook, Gopalan, Berlin, & Matthews, 1991).

Additionally, incomplete reporting of trials may have the same effect as other types of publication bias. Trials often measure outcomes at several time points with several instruments, and researchers often conduct multiple analyses. Because researchers select large and significant results for publication, the published record systematically overestimates intervention effects (Chan, Hrobjartsson, Haahr, Gotzsche, & Altman, 2004; Counsell, Clarke, Slattery, & Sandercock, 1994). For example, a study of the antidepressant paroxetine reported that it was effective in reducing depression with minimal adverse effects (Keller et al., 2001). Complete results retrieved through litigation (Kesselheim & Avorn, 2007) showed no significant benefit over placebo for any of the eight prespecified outcomes, and people receiving the drug experienced more adverse events such as self-harm (Beecham & SmithKline, 1998). By including only 15% of outcomes measured, the published report misled readers about the true results of the study (Jureidini, McHenry, & Mansfield, 2008).

The Importance of Negative Results

Today, a few dozen pharmaceutical manufacturers conduct or sponsor the majority of drug trials. Almost all trials of a new medication will be conducted by the developer and patent holder, so researchers know where to look for information about these trials. To obtain marketing authorization for new products, companies are required to submit confidential data and prespecified analytic plans to regulators, which can often be obtained by researchers. These circumstances make it possible to identify and to compare trial protocols with published reports, thus providing researchers with a tool to detect publication bias in drug research.

By comparison, numerous independent researchers conduct social work research, and many groups study similar interventions. Except for the purpose of ethical approval, social work researchers may never submit their plans for external review. Identifying all the studies that have evaluated a particular intervention can be extremely challenging. For these reasons, it is almost impossible to evaluate the true prevalence of reporting bias in social work at this time.

Selective publication—known also as the ''file drawer problem'' (Rosenthal, 1979)—has been acknowledged for decades, and empirical evidence still shows it is a current problem in various fields (Dwan et al., 2008; Dwan, Gamble, Williamson, & Kirkham, 2013). Despite their importance, negative results are still undervalued by journals that preferentially publish statistically significant results. Several examples in social work research highlight how the publication of negative effects can be just as important as the publication of positive results. For example, the Cambridge-Somerville Youth Study, completed in 1945, was a randomized controlled trial of a social work intervention for at-risk boys (Powers & Witmer, 1951). As adults, men who received the intervention as boys said that it helped them lead better lives (McCord, 1978). However, comparisons between treatment and control groups indicated that they were more likely to have been convicted of a crime, to abuse alcohol, to have a severe mental illness, and to die early (McCord, 1978). Furthermore, men who received more of the intervention were more likely to have adverse outcomes (McCord, 1978). Publication of these negative results, and additional research to understand them, likely prevented further harm to vulnerable children.

The ''file drawer problem'' (Rosenthal, 1979) also reduces the power of meta-analysis to identify positive or negative effects. A review of Scared Straight by Petrosino, Turpin-Petrosino, and Buehler (2002) demonstrates how valuable such results are for secondary research. ''Scared Straight'' is a juvenile awareness program that aims to reduce reoffending by giving at-risk youth a firsthand experience of prison. However, when Petrosino and colleagues (2002) conducted a systematic review of Scared Straight, they found nine trials that collectively showed the intervention *increases* reoffending. Most studies did not report statistically significant results, so a meta-analysis of several small studies was essential to resolve the uncertainty about the program's effects. If negative or nonconfirmatory results continue to be filed away without publication, harmful intervention programs will continue to be rolled out unintentionally.

The Development of Trial Registration

The harmful effects of some interventions are primarily known because researchers have published unexpected negative results. Due to lack of publication or underreporting, harmful effects of other interventions have certainly been missed. Furthermore, many ineffective interventions appear to be effective based on published reports that do not contain the full results.

Fortunately, reporting bias can be reduced. If investigators would record the design of all trials before beginning recruitment, researchers and practitioners could find all trials that have been conducted using a permanent and publicly accessible database (Simes, 1986). The FDA Modernization Act (U.S. Congress, 1997) aimed to establish such a database with the launch of ClinicalTrials.gov in 2000. To encourage registration, the International Committee of Medical Journal Editors required that trials had to be prospectively registered to be considered for publication (De Angelis et al., 2005), requiring information about 20 items (Table 1). Trials can be registered on several databases; of these, ClinicalTrials.gov is the largest with approximately 143,000 study records from 183 countries.

Table 1. Minimal Registration Data Set.

WHO Trial Registration Data Set
1. Unique trial number
2. Trial registration data
3. Secondary IDS
4. The funding source(s)
5. Primary sponsor
6. Secondary sponsor(s)
7. Responsible contact person
8. Research contact person
9. The title of the study
10. The official scientific title of the study
11. Research ethics review information
12. Condition being studied
13. Intervention(s)
14. Key inclusion and exclusion criteria of participants
15. Study type
16. Anticipated trial start date
17. Target sample size
18. Recruitment status
19. Primary outcome (and intended time-points)
20. Key secondary outcomes

The data fields were specified at a meeting convened by the World Health Organization (WHO) in April 2004.

Prospective trial registration quickly became an accepted part of biomedical and public health research. For example, the Consolidated Standards of Reporting Trials (CONSORT) Statement is an evidence-based guideline for reporting trials; it is the international standard for reporting trials in medicine, and it is endorsed by over 600 journals and editorial groups. In 2010, CONSORT emphasized the importance of trial registration by adding ''Trial registration number and name of trial registry'' as a required item for all clinical trials (Schulz, Altman, & Moher, 2010). Reports of social and psychological interventions continue to omit information that is essential to understand their conduct and results (Grant, Mayo-Wilson, Melendez-Torres, & Montgomery, 2013), so leading journals in social work, including *Research on Social Work Practice*, are currently developing a CONSORT guideline for social and psychological interventions (Grant, Mayo-Wilson, Hopewell, et al., 2013; Montgomery et al., 2013). Following the extension of such guidelines to social work, prospective registration may soon be expected as well.

Registering a Trial

Registering a trial may take no more than 20 min (Zarin & Keselman, 2007) and should occur after ethical approval has been obtained but before recruitment begins. Registration through ClinicalTrials.gov is done through a Web-based protocol registration system, which begins with a ''quick start guide'' that leads the user through each stage of trial registration (Table 2). The system asks users to enter key details including the study eligibility criteria, a description of the intervention and comparator, target sample size, dates of recruitment and completion, and the primary and secondary outcome measures. Each trial is assigned a unique number that can be included and linked to future reports, and each record is made public following review by quality assurance personnel. Users can update records as trials progress by adding results of the trial, citations to publications, or changes to the protocol. These changes are publicly archived to form a complete record of the trial's progress from design to implementation.

Table 2. How to Register a Clinical Trial.

Steps for Registering a Clinical Study on clinicaltrials.gov
1. Log in to protocol registration system (PRS)
2. Enter the required and optional data (for help, use the "Quick Start Guide")
3. After entering data, preview and check for accuracy
4. Submit the record
5. The record will appear in 2–5 business days
6. Modify and add results using the record identification number

Note. For more information, http://prsinfo.ClinicalTrials.gov or e-mail register@ClinicalTrials.gov.

The time required to register a trial is minimal, and the benefits of registration are multiple. By registering trials, researchers increase the visibility of their work, and they can demonstrate that they have followed best practices for conducting and reporting trials. Practitioners can use trial registries to identify the best current evidence to help service users, and systematic reviewers can utilize registries to identify published, unpublished, and ongoing trials. Funding bodies can use trial registries to assess research activity and ensure effective allocation of funds. Broadly, transparent and open reporting encourages public confidence in research and practice.

In addition to the practical benefits, trial registration fulfills ethical obligations between researchers and research participants (Zarin & Keselman, 2007). Participants in trials risk the consequences of untested interventions and delays in treatment in order to generate evidence that will help people with similar problems; reporting trials accurately and completely is required to fulfill the agreement that researchers make with people who participate in research.

Conclusion

In addition to academic efforts to monitor and to promote trial registration, public campaigns are currently encouraging governments, regulators, and research bodies to implement measures necessary for the registration of all past, present, and future trials (Goldacre, Heneghan, Godlee, & Chalmers, 2013). Fewer than half of published trials may be adequately registered today (Mathieu, Boutron, Moher, Altman, & Ravaud, 2009), but prospective registration is quickly becoming a normal part of all research involving human participants.

To conduct ethical and valid trials, social work researchers can easily register all randomized trials before recruiting participants. To promote best practices, journal editors could

encourage or require authors to report trial registration numbers in all reports of randomized trials.

Declaration of Conflicting Interests

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